



CANADIAN BLOOD SERVICES

The Blood Supply System in Canada

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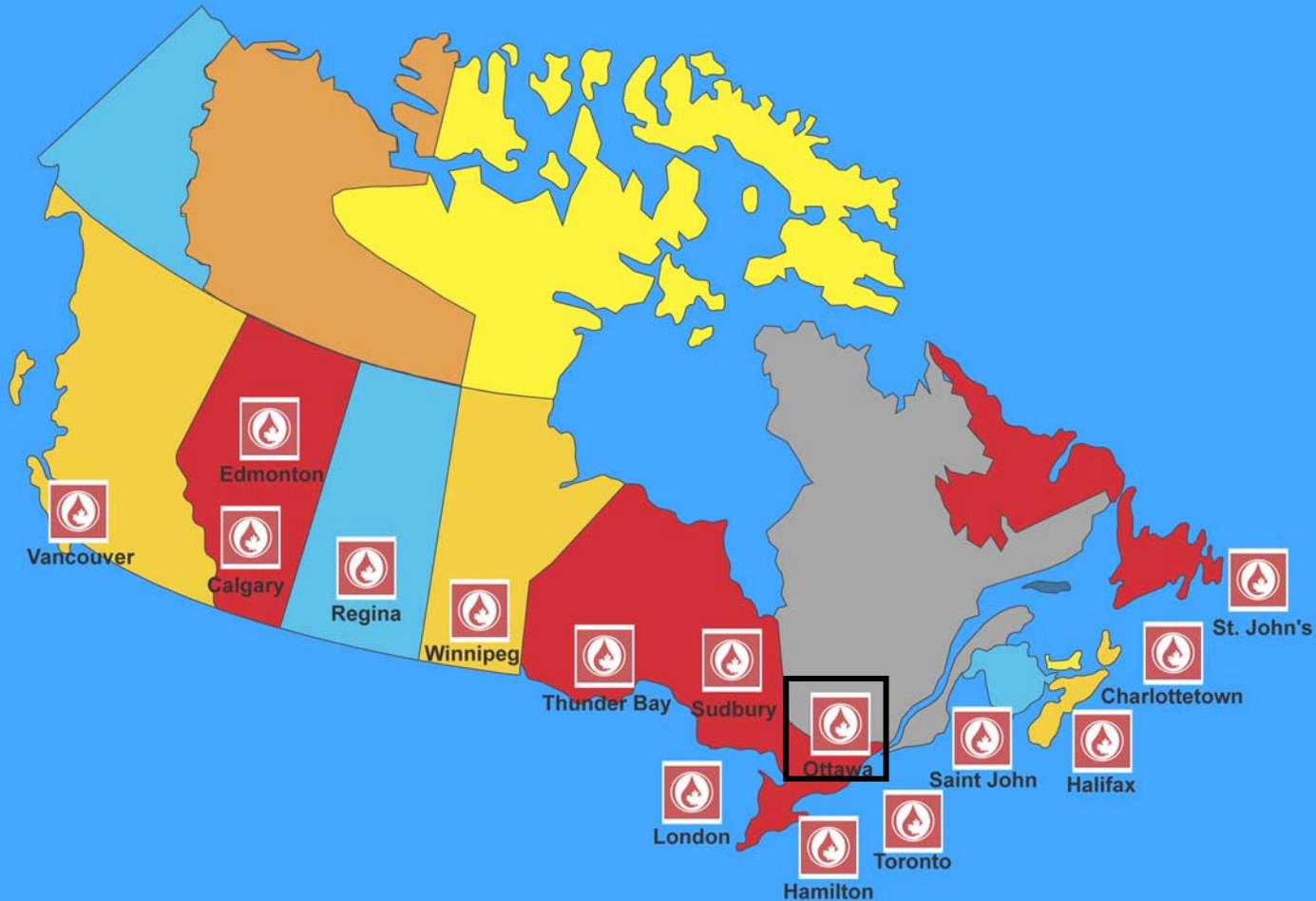
Overview

- What is Canadian Blood Services?
- Historical background
- Current supply issues
- Today's questions:
 - National Blood Policy
 - Government's role in daily supply of blood and plasma
 - Government's role during local or national disaster
 - Needs of the military
 - Government's role in monitoring and tracking blood supply

What is Canadian Blood Services?

- National, independent, not-for-profit, charitable organization
- Mandate:
 - Manage a safe, secure and accessible supply of blood and blood products for all Canadians (excluding Province of Quebec)
 - Core functions of recruitment, collection, manufacturing, testing and distribution
 - Related functions of research & development, education, utilization management and diagnostic services
 - Manage the Unrelated Bone Marrow Donor Registry

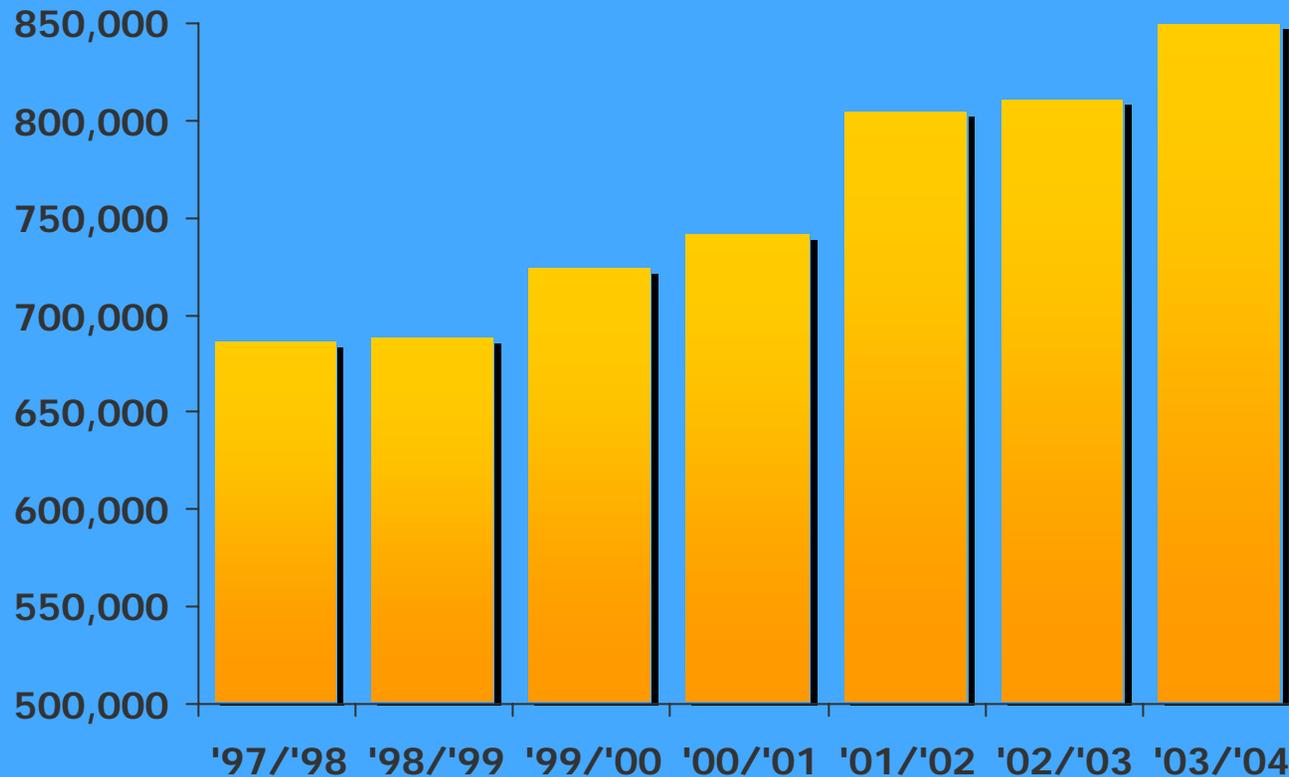
Canadian Blood Services



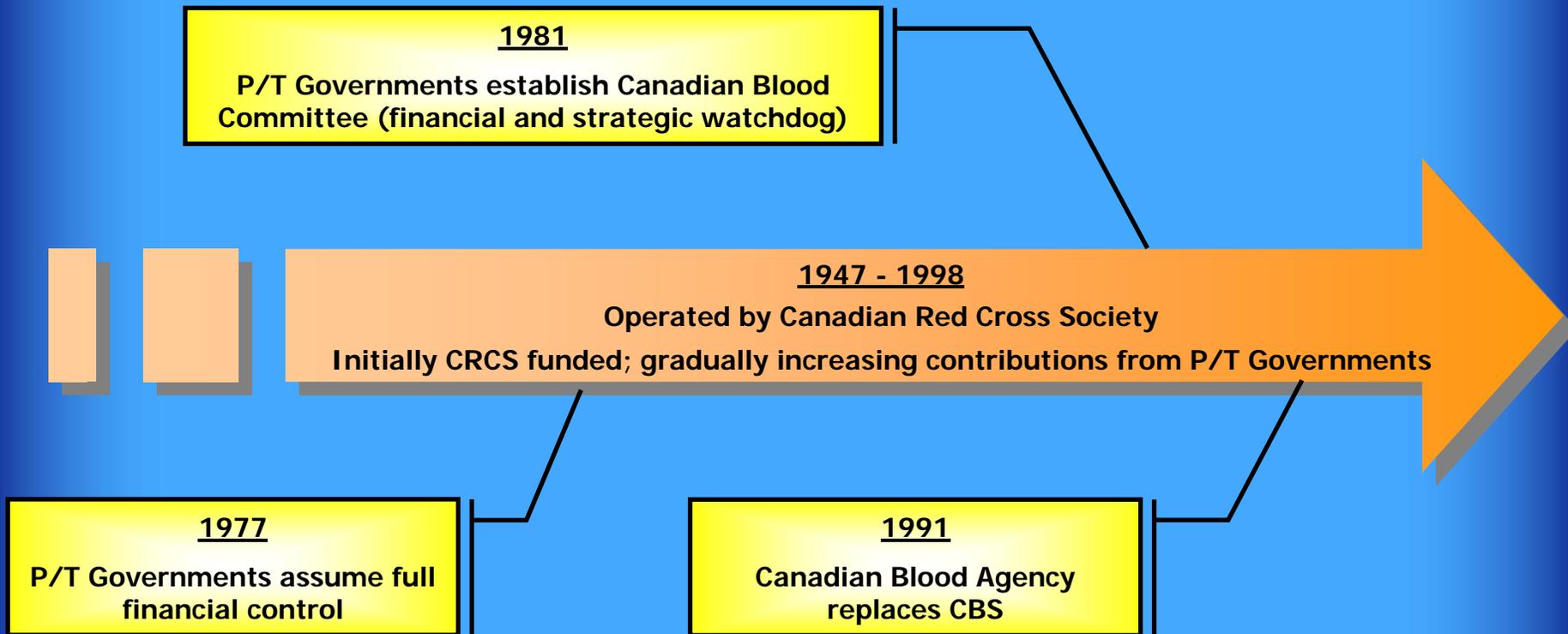
Canadian Blood Services

Funded by all Provinces and Territories (except QC)	14,000 collection clinics annually
Global operating budget FY04 = C\$830 million	1.4 million blood donors (450,000 are 'active')
4,700 employees, 17,000 volunteers	900,000 collections annually
Arm's length, not-for-profit agency "independent" of government	Serves 855 hospitals across Canada
40 fixed facilities	Some 600,000 transfusion recipients per year

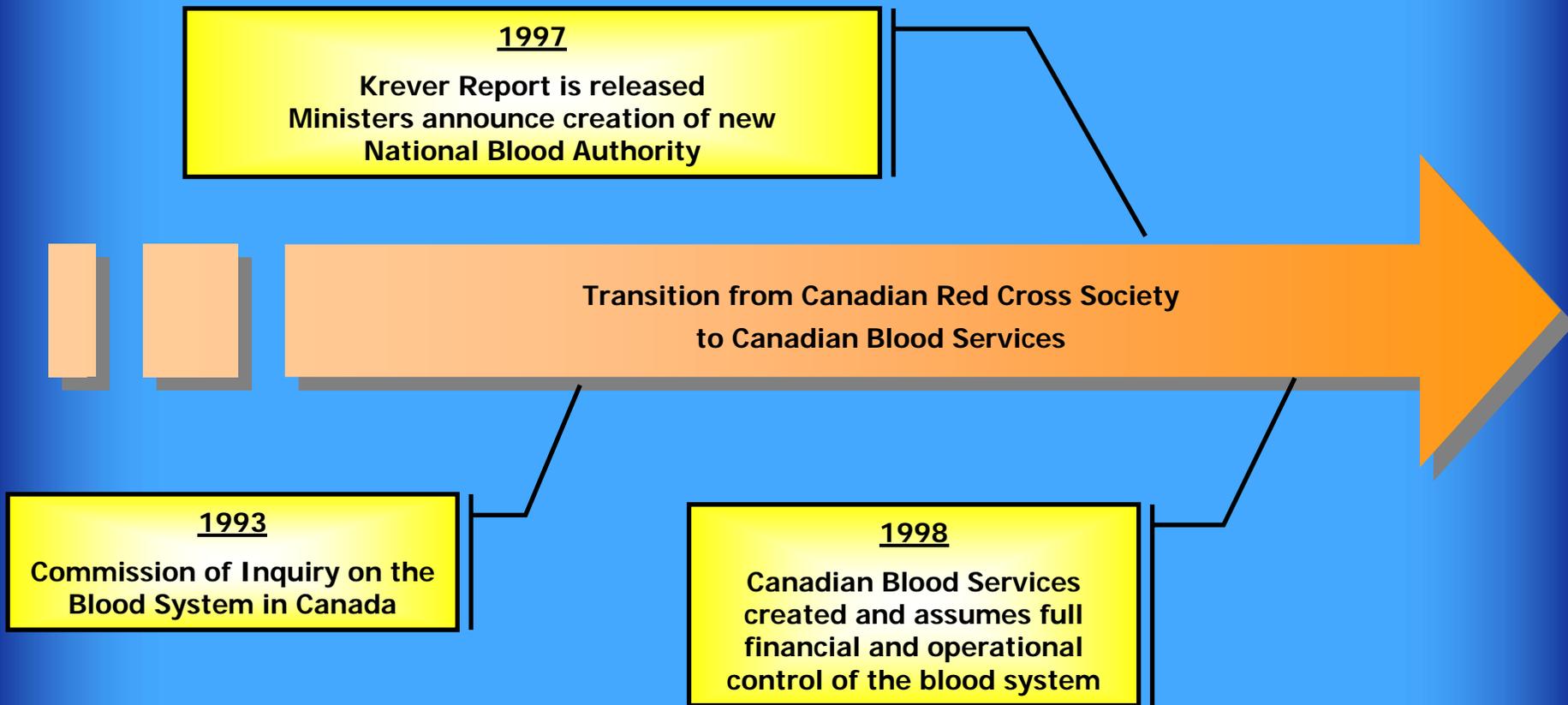
Annual WB Collections FY98 – FY04



Historical Background



Historical Background



A legacy of scandal and failure...



Historical Background

- Memorandum of Understanding between the Federal, Provincial and Territorial Ministers of Health (F/P/T MoU) is signed in late 1997
 - Defines their respective roles and responsibilities in the national blood system
 - Outlines the functions and structure of a National Blood Authority
 - Provides governance framework of all aspects of the system

National Blood Policy



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National Blood Policy

- There is no national blood policy *per se*
 - previous efforts at creating a Federal Act have been unsuccessful
- F/P/T Memorandum of Understanding essentially ascribes the national blood policy
- In the MoU, the Ministers declared that the new blood system would be governed by the following 4 principles:
 1. *The safety of the blood supply is paramount*
 2. *A fully integrated approach is essential*
 3. *Accountabilities must be clear*
 4. *The renewed blood system must be transparent*

National Blood Policy

- In addition, the 7 principles adopted by the F/P/T Ministers in 1989 apply:
 1. *Voluntary system should be maintained and protected*
 2. *National self sufficiency in blood and plasma collections should be encouraged*
 3. *Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged*

National Blood Policy

- Ministerial Principles (cont/d):
 4. *Safety of all blood, components and plasma fractions should be paramount*
 5. *Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained*
 6. *A cost effective and cost-efficient blood supply program for Canadians should be encouraged*
 7. *A national blood supply program should be maintained*

National Blood Policy

- Functions of national blood authority (CBS) detailed in the MoU:
 - Will provide for the following core operational functions in a *fully integrated fashion*:
 - donor recruitment and management
 - whole blood and plasma collection
 - testing and laboratory work
 - processing
 - storage and distribution
 - inventory management

National Blood Policy

- In support of the core operational functions, the NBA will provide for the following key functions:
 - standard, policy and guideline setting supplementary standards
 - coordinating a national program in research and development
 - surveillance and monitoring
 - professional and public education and information
 - health risk management

Role of Governments

Role of Governments

- The Canadian blood system developed and put in place in 1998 comprises the following major components:
 - Federal Government:
 - *through the Minister of Health, assumes the functions of setting up regulations for the safety of the system and of inspecting the blood manufacturing facilities*
 - Provincial and Territorial Governments:
 - *Ministers of Health are the Corporate Members (“shareholders”)*
 - Blood Operators:
 - *Canadian Blood Services (and Hema-Quebec)*

Role of P/T Governments

- Provincial and Territorial Ministers of Health, as Corporate Members of CBS, are responsible for its funding and for defining its mission and mandate
- However, MoU clearly articulates:
 - “CBS is not an agent of any government”
 - “... operates at arm’s length from its corporate members”

Role of P/T Governments

- As CBS Corporate Members:
 - Play a role similar to shareholders of a corporation
 - Responsible for the overall expenditure of public funds by CBS in delivering the blood program
 - Appoint the Board of Directors
 - Approve the CBS Corporate Plan and global budget request on an annual basis
 - May conduct independent management audits from time to time

Role of P/T Governments

- As Ministers of Health:
 - Responsible for administration of their respective health care systems in each jurisdiction
 - Responsible for public health measures, including appropriate monitoring and reporting of diseases caused by blood-borne pathogens
 - Use their “best efforts” to ensure that health care facilities and institutions cooperate fully with CBS
 - Will consider and pursue the implementation of any further measures required for the operation of CBS

Role of Federal Government

- Minister of Health responsible for the administration of the *Food and Drugs Act*, under which all regulatory statutes for the national blood system derive
- Also responsible for the conduct of national surveillance activities
- Provides no funding for the national blood system apart from an annual \$5M grant for research and development

Role of Governments in the supply of blood components

- No *direct role* played by either Federal or Provincial / Territorial governments
- Federal Government (Health Canada) ensures consultation with Operators regarding the impact on the blood supply of directives under review (e.g. vCJD policies)
- P/T governments may impact the blood supply through investment in healthcare service delivery
 - *Common for major investments (e.g. new cancer treatment centres or cardiac surgery units) to be implemented without consideration on blood supply*
 - *No mention in the MoU of the roles of F/P/T governments in blood supply*

Role of Governments in the supply of plasma and plasma derivatives

- Unlike in fresh components, Canada is not self sufficient in plasma for fractionation
- Sufficient Canadian plasma for custom fractionation of 20% of IVIG needs
 - almost 100% albumin needs are met
 - fVIII in Canada is ~100% recombinant
- Remaining IVIG needs purchased on commercial market
- Despite Ministerial Principles espousing self sufficiency in plasma, there has been reluctance of P/T Governments to invest in plasma acquisition
- No large scale fractionation facility in Canada (except for Cangene)

Role of Canadian Blood Services in supply of blood and plasma

- Operator assumes full responsibility for ensuring adequacy of supply of fresh components and plasma derivatives:
 - Targets
 - minimum 4 days inventory of red cells (by blood group) in CBS' inventory
 - 11 – 12 weeks inventory of most plasma derivatives and recombinant proteins in CBS' inventory
 - Actual inventories are shared with all levels of governments and hospital customers on bi-weekly basis
 - Hospitals determine and carry their own inventories of cellular components and derivatives
 - Outdating information shared with CBS
 - No formal supply agreements with hospitals

Forecasting of blood product requirements

- Stochastic forecasting:
 - Standard method of short-term prediction
 - Used by many blood centres, NBDRC (until 2003)
 - Extrapolates into the future based on blood use patterns from the past
 - Most accurate for the first year; becomes less accurate for each subsequent year
 - Works well as long as change in the patterns of use is minimal
 - Modest data requirements

Causal forecasting

- Has all the predictive capacity of stochastic forecasting, PLUS can incorporate changes that are going to occur
 - e.g. increase in blood use will be expected as baby boomers age
- Hence
 - is more accurate over the longer terms (5 – 10 years)
- More elaborate data requirements

Causal forecasting in Canada

- Canadian Blood Services has *actual* collection data from all Blood Centres
 - NBDRC used collection data from sample of blood centres, hence *estimated* US blood collections
- Patient-level blood use from every patient
 - Currently available in British Columbia
 - Other provinces developing similar centralized transfusion registries (supported by Provincial governments)
- Plans:
 - Develop causal forecasting models for all products (including plasma derivatives)

Role of Governments in blood supply during disaster

- Disaster planning for the blood supply in case of disasters is the responsibility of Canadian Blood Services
- CBS is linked to both Federal and Provincial Emergency Response Organizations
 - linkages did not operate optimally in the hours / days post 9/11
 - efforts continue to strengthen and monitor those linkages
- No national reserves in Canada
- No specific plans to estimate blood requirements for possible terrorist activities
 - adequacy not the issue
 - transportation, logistics, coordination with Emergency Response Organizations

Role of Canadian Blood Services in inventory management

- CBS has moved over the past 5 years from a system that was managed locally, to a *nationally managed inventory* of blood components
- Fresh components are routinely moved from city to city, and across Provincial borders without restriction
 - Standard, routine import / export patterns between blood centres
 - National inventory manager can direct inventory to needed location
- Inventory of plasma derivatives is managed on a national basis
 - central warehouse carries bulk of inventory
 - regional and local warehousing of smaller inventories
- National inventory management has permitted sustained blood supplies during:
 - Prolonged labour disruptions, August 2003 blackout, regional shortages etc

Needs of the Military

- Canadian Armed Forces do not have independent blood supply
- All blood needs are provided by Canadian Blood Services (and Hema-Quebec) through local blood centres
- CBS partners with CAF in blood drives
- Largest deployment of Canadian troops is currently in Afghanistan
 - Routine monthly shipments of Group O red cells, plus any other needs as required

Role of Government in monitoring and tracking blood supply

- No specific role of Federal or Provincial government in tracking / monitoring supply
- CBS provides information on plasma derivative inventories to all stakeholders on bi-weekly basis
- During actual or potential supply disruptions (e.g. strikes, blackouts etc), Regulator requests detailed information on fresh component supply
- Supply agreements exist between CBS and Hema-Quebec, permitting exchange of cellular components and / or plasma derivatives as required

Summary

- Canadian Blood Services operates a national blood supply system, responsible for all collections and all hospital needs in entire country
 - (Hema-Quebec has similar mandate in QC)
- CBS also responsible for acquisition of all plasma derivatives and recombinant proteins and distribution to hospitals / clinics
 - either through custom fractionation contracts or commercial purchasing contracts

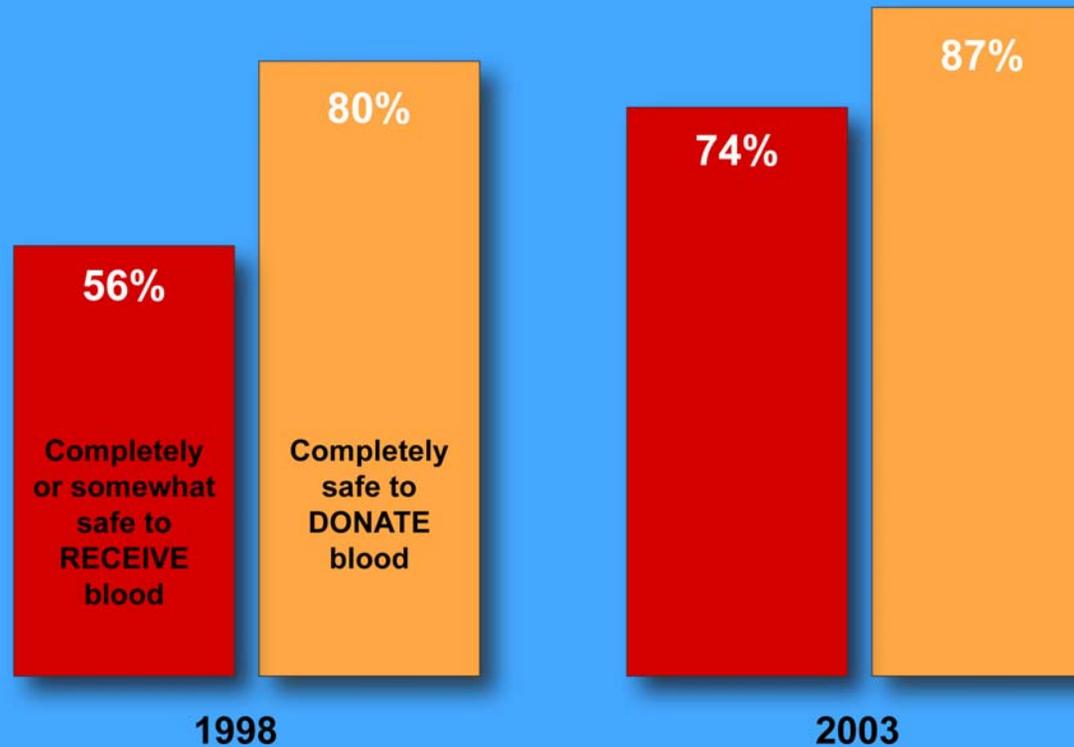
Summary

- Canada does not have a National Blood Policy *per se*
 - for Canadian Blood Services, a *Memorandum of Understanding* signed by Federal and Provincial governments provides governance, financial, policy and operational framework in which to operate the blood supply system

Summary

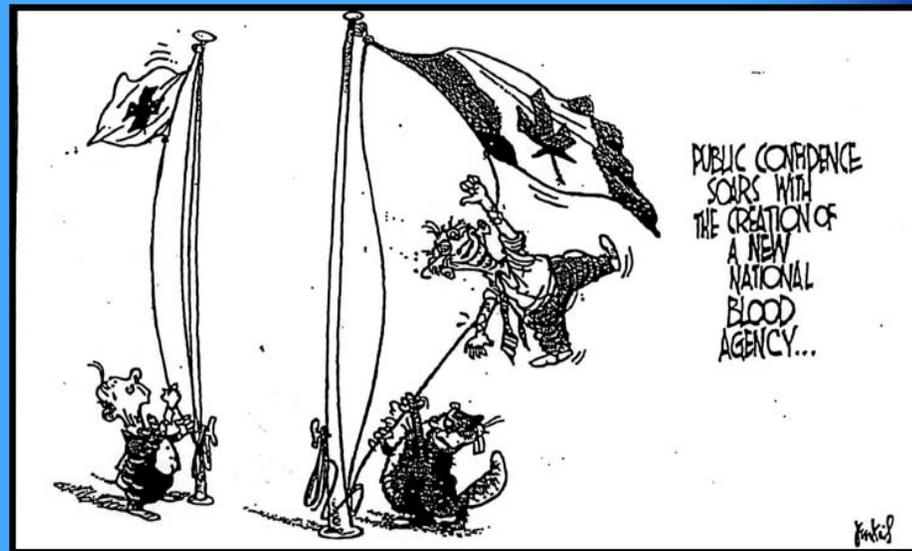
- Whole blood collections in Canada have increased 25% over past 5 years (following 10 year long decline under previous Operator)
- Canada's self sufficiency in plasma for fractionation remains poor
- Management of blood and plasma inventory on a national basis over past 5 years has:
 - greatly minimized shortages (virtually no delays in elective surgeries)
 - permitted stable supply during significant disasters or disruptions

CBS is rebuilding public trust



Public opinion of the blood system in Canada

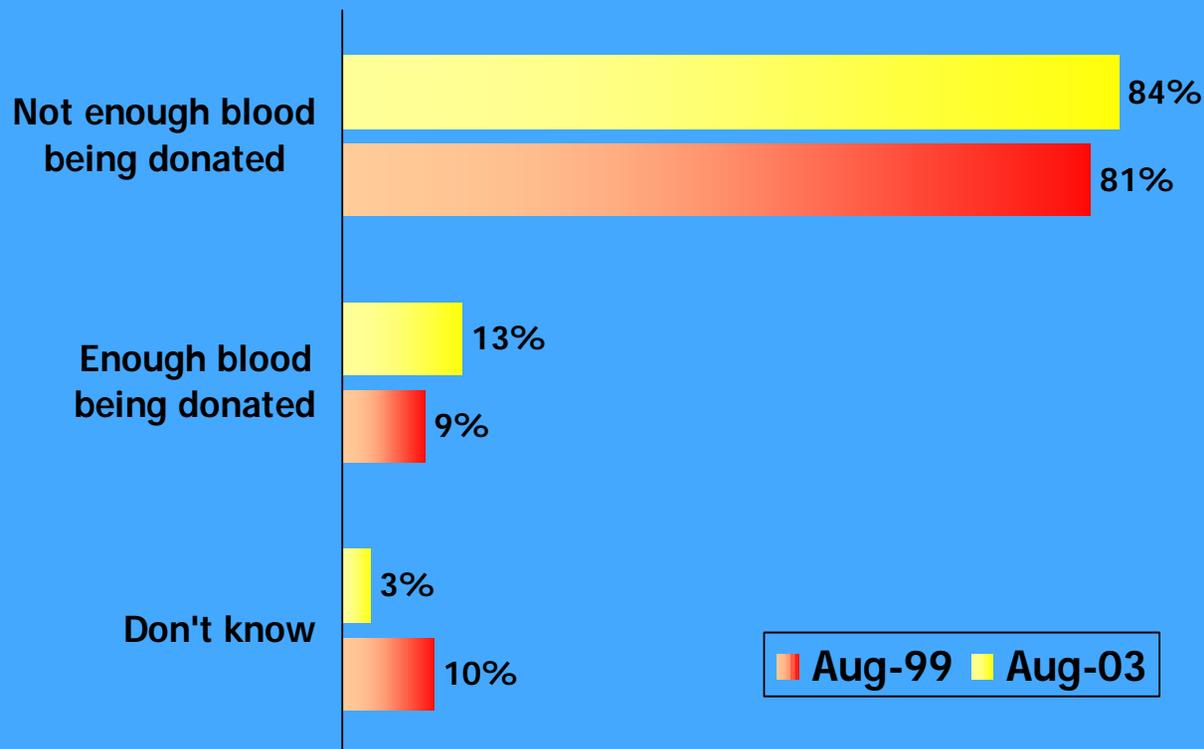
- “The last five years have seen blood collection in Canada move from being a front page disaster to a mid page success story”
- “Confidence in the system has been restored”
- “It is important to note that this has taken place during a time in which there’s been an increasing tendency for the public to question authority in the public system”



Ipsos-Reid, independent polling, August 2003

The challenge continues

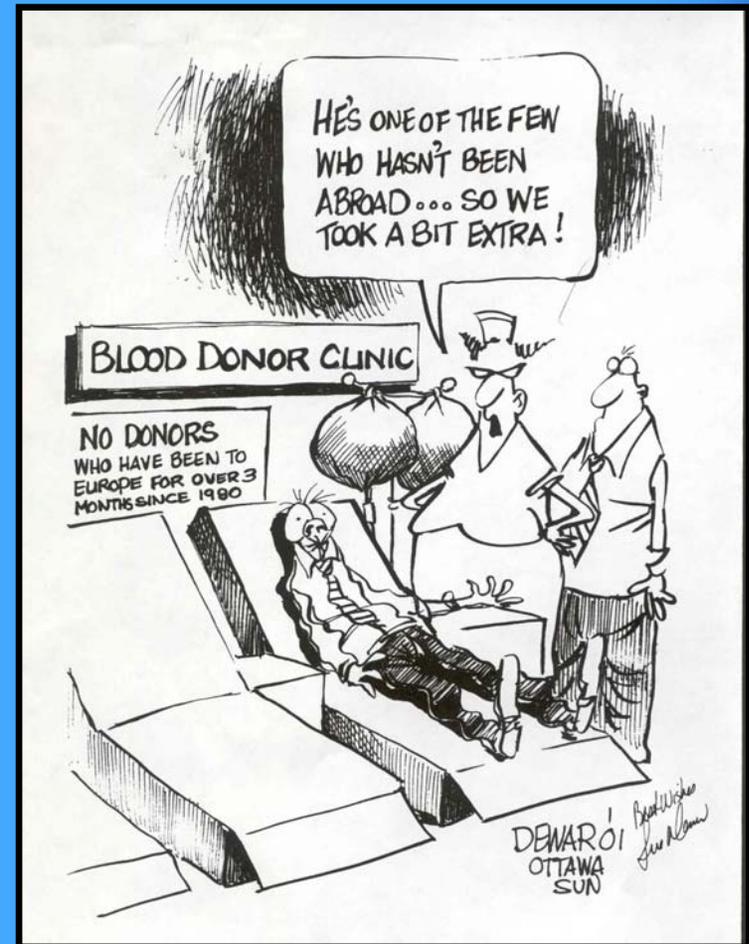
POLL: Do you think there is enough blood being donated across Canada?



Paradoxically, most Canadians (78%) believe there would be enough blood if they needed it

Conclusion

- Absent a more formal role of Government in the supply of blood components and plasma derivatives, the Federal and Provincial Governments should:
 - assume a far more active position in promoting the need for blood and the importance of donations
 - ensure regulatory requirements address appropriately the balance between supply and demand
 - ensure adequate funding of system to permit both safety and security of supply
 - promote appropriate utilization



Conclusions

- With acknowledgements to all the:
 - Donors
 - CBS staff
 - CBS volunteers
 - Funding governments

